PTO/SB/17 (10-02)
Approved for use through 10/31/2002. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2003

Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT | ($) 740

Complete if Known	
Application Number	09/432,881
Filing Date	November 2, 1999
First Named Inventor	Markey, Micheline
Examiner Name	Nguyen, H.
Group Art Unit	1617
Attorney Docket No.	015662-000900US

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit Card ☐ MoneyOrder ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 20-1430

Deposit Account Name: Townsend and Townsend and Crew LLP

The Commissioner is authorized to: *(check all that apply)*

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	740	2001	370	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	510	2003	255	Plant filing fee	
1004	740	2004	370	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims	Fees from below	Fee Paid
Total Claims		-** =		X =	
Independent Claims		-** =		X =	
Multiple Dependent				X =	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	400	2252	200	Extension for reply within second month	
1253	920	2253	460	Extension for reply within third month	
1254	1,440	2254	720	Extension for reply within fourth month	
1255	1,960	2255	980	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,280	2453	640	Petition to revive – unintentional	
1501	1,280	2501	640	Utility issue fee (or reissue)	
1502	460	2502	230	Design issue fee	
1503	620	2503	310	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Petitions related to provisional applications	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	740	2809	370	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	740	2810	370	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	740	2801	370	Request for Continued Examination (RCE)	740
1802	900	1802	900	Request for expedited examination of a design application	
				Other fee (specify)	

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3)** ($)740

SUBMITTED BY				Complete *(if applicable)*	
Name (Print/Type)	Joel G. Ackerman	*Registration No. (Attorney/Agent)*	24,307	*Telephone*	415-576-0200
Signature				*Date*	12/06/02

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PTO/SB/21 (06-00)
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/432,881
Filing Dat	November 2, 1999
First Named Inv ntor	Markey, Micheline
Group Art Unit	1617
Examiner Name	Nguyen, H.
Total Number of Pages in This Submission: 8	Attorney Docket Number: 015662-000900US

ENCLOSURES *(check all that apply)*

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment / Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s)
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) *(please identify below)*:

Return Postcard; **Request for Continued Examination**

Remarks: The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	Townsend and Townsend and Crew LLP Joel G. Ackerman Reg. No. 24,307
Signature	
Date	12/06/02

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on this date: 12/06/02

Typed or printed name	Nikki Newell		
Signature	Nikki Newell	Date	12/06/02

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SF 1413012 v1

#21
12/18/02

PATENT

Attorney Docket No.: 015062-000900US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Examiner: Nguyen, H.
MICHELINE MARKEY et al.	Art Unit: 1617
Application No.: 09/432,881	
Filed: November 2, 1999	
For: PHARMACOLOGICAL INDUCEMENT OF THE FED MODE FOR ENHANCED DRUG ADMINISTRATION TO THE STOMACH	**REQUEST FOR CONTINUED EXAMINATION** EXAMINING GROUP 1617

Box AF
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Final Office Action mailed May 23, 2002, Applicants hereby request continued examination of this Application on the basis of the comments herein and the attached materials.

In response to previous comments of the examiner, Applicants acknowledge that the claims under examination in this application are composition claims rather than method claims. Nonetheless, the composition as recited in the instant claims is indeed distinct from the compositions of the references, and from any composition that might be suggested by the references in combination, even if such combination were proper. The limitations of Applicants' claims that are not met by the references are the recitation in claim 1 that the fed mode inducing agent is combined with a solid matrix that releases a drug when the matrix is in the stomach and that is large enough when in the stomach to promote gastric retention during the fed mode.

Acharya et al. contains disclosures relating to controlled release formulations of active ingredients in general, and to a specific type of such formulation in particular. However, the effective disclosure of Acharya et al. – the information that would be regarded as credible by those skilled in the art – relates to controlled release formulations that are designed for use in ~~connection with mucous membranes of the~~ body.

The most specific type of dosage form that is disclosed and is highly emphasized by Acharya et al. is one that is specifically formulated and configured for drug delivery in the mouth. The component in the Acharya et al. dosage form that controls the situs and manner of drug release is calcium polycarbophil, which is a bioadhesive typically used in vaginal products because of its tendency to adhere to the vaginal wall. As known in the art, polycarbophil adheres to mucous membranes in general. To corroborate this, Applicants submit the accompanying materials, downloaded from the Internet, that discuss polycarbophil and how it functions in the products currently on the market in which it is used. The examiner is requested to make these materials of record. The pertinent disclosures in these materials are as follows:

> The literature on *Replens* Vaginal Moisturizer downloaded from the Yahoo Shopping website explains that polycarbophil "adheres to the epithelial cells lining the vaginal walls and ... is detached only upon the shedding of the outer layer of cells or mucin, a normal healthy process which occurs every 2 or 3 days."
>
> The literature on Progesterone bioadhesive vaginal gel downloaded from Columbia Laboratories' website states that "Polycarbophil was designed to mimic negatively charged mucin, the glycoprotein component of mucous [*sic*, mucus] which is responsible for the attachment of mucus to underlying epithelial surfaces."

Carbophil performs that same function in the dosage form disclosed by Acharya et al. except that the mucous membrane in Acharya et al. is the inside of the

mouth rather than vaginal tissue. The dosage form is placed in the mouth for oral, gingival, or buccal delivery of the drug, this localized delivery being the result of the adherence of the polycarbophil to the oral, gingival, or buccal areas for an extended period of time (see column 3, lines 38-42). Further confirmation by Acharya et al. that the dosage form is one that remains in the mouth are found at column 7, lines 14-17, in the statement: "Most preferably, the shape of the polycarbophil follows the natural contour of the mouth ...," and at lines 31-33, in the statement: "While so present the hydrated polycarbophil acts to humidify the mouth, while in some instances also stimulating saliva production." All of these effects are achieved as a result of the retention of the dosage form in the mouth. Thus, the drugs that are disclosed in Acharya et al. are not "retained in a solid matrix in a manner causing release of said drug from said solid matrix when said solid matrix is in the stomach ...", as required by the present claims. Instead, they are retained in a solid matrix in a manner causing release of the drugs in the mouth, or alternatively, another mucous membrane – but not the stomach. This is a difference in the matrix itself, specifically in its composition, not in the manner in which the matrix is used. There is no suggestion that any of the drugs listed by Acharya et al. would serve any purpose in a matrix that releases the drug in the stomach rather than in the mouth.

Combining the Acharya et al. disclosure with that of Shell amounts to considering a dosage form that is specifically designed to remain in the stomach together with one specifically designed to remain in the mouth. The two references disclose controlled release formulations for different applications. Each type of formulation has specific characteristics that make it suitable for use in those applications. It is neither logical nor likely that one skilled in the art would take ingredients from one formulation and transfer them to the other with the expectation that their usefulness or the function served by their presence in the mouth or another mucous membrane would be the same in the stomach. Accordingly, the combination of Shell and Acharya et al. does not lead one

skilled in the art to include docusate, or any of the drugs disclosed by Acharya et al. in a gastric-retentive dosage form such as that disclosed by Shell.

As previously noted, the Sewester et al. disclosure describes docusate as a fecal softener, a function that is served in the colon. Acharya et al. themselves state that it is a laxative. For effective use in a controlled release formulation, a laxative should be formulated so as to be released in the colon. That, for instance, may be the reason for the mention in Acharya et al. of formulations that are a suppository (col. 5 line 34).

However, release of sodium docusate [or another fed mode inducer] into the colon would not produce the desired fed mode inducing effect in the claimed compositions. In order for the fed mode inducer of the claimed compositions to be effective as such, it must be released into the region extending from the stomach through the duodenum to the upper part of the small intestine [see the specification, at p.19 lines 19-21].

As in the case of Acharya et al., Sewester et al. do not suggest the inclusion of a fecal softener in a controlled release dosage form that releases the docusate anywhere other than in the colon. Combining Sewester et al. with the other two references amounts to considering a fecal softener that is specifically designed to act in the colon in combination with a dosage form that is specifically designed to deliver drugs to the stomach (Shell) where the docusate will not serve its known function, and also with a dosage form that is specifically designed to act in the mouth or other mucous membranes (Acharya et al.) and not in the stomach.

The only common ground among these references is that the active ingredients are biologically active and that the formulations of Acharya et al. and Shell are designed for controlled release. Aside from that, the disclosures are in direct contradiction to each other since each is focused on a distinct and different portion of the gastrointestinal tract and the results achieved are specifically intended to occur only in those portions of the tract. There is no suggestion or motivation in any of the references to take a biologically active ingredient from a dosage form that restricts delivery of the

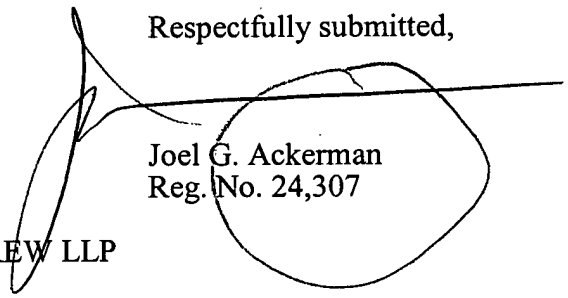
active to the mouth and place it in a dosage form for delivery into the region extending from the stomach through the duodenum to the upper part of the small intestine, or to take a specific biologically active ingredient that is known for its action in the colon (docusate) and place it in a dosage form for delivery to that region.

For these reasons, the combination of these references is not appropriate and does not render obvious the invention recited in Applicants' claims. Accordingly, reconsideration and allowance is respectfully requested.

Applicants also wish to point out that the election by Applicants in Paper No. 7 of docusate as a single disclosed species was a provisional election in accordance with MPEP 803.02 for the examiner to use as a starting point for a search. Since for the reasons explained above the generic claim to the extent of its coverage of docusate is allowable over the prior art, the search and examination should now be extended to include the remaining non-elected species.

Should any matters remain that can be resolved by a conference, the examiner is encouraged to telephone the undersigned at 415-576-0200.

Respectfully submitted,



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